# APPENDIX A: 510(K) SUMMARY

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| **Submitter** | Guidant Corporation, Cardiac Surgery |
| **Submitter's Address** | 3200 Lakeside Drive<br>Santa Clara, CA 95054 |
| **Telephone** | (408) 845-2014 |
| **Fax** | (408) 845-2077 |
| **Contact Person** | M. Laurie Wong |
| **Date Prepared** | August 19, 2005 |
| **Device Trade Name** | Guidant VasoView® HemoPro™ Endoscopic Vessel Harvesting System |
| **Device Common Name** | Electrosurgical cutting and coagulation device and accessories |
| **Device Classification Name** | Electrosurgical cutting and coagulation device and accessories |
| **Device Classification** | Class II |
| **Summary of substantial equivalence** | The design, materials, method of delivery, and intended use features of the Guidant VasoView® HemoPro™ Endoscopic Vessel Harvesting System are substantially equivalent with regard to those features in the predicate devices: the VV4 (K030512, May 14, 2003), and the VV6 (K041981, August 20, 2004). |
| **Device description** | The Guidant VasoView® HemoPro™ Endoscopic Vessel Harvesting System is designed for use in conjunction with the 7 mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and VasoView® HemoPro™ Harvesting Tool for cutting and sealing of vessel branches. The C-Ring/distal lens washer is independently controlled by a C-Ring Slider on the handle of the device that retracts the vessel and washes the distal tip of the Endoscope. The Harvesting Tool can be extended/retracted from the main cannula by inserting it into the Tool Adapter Port, and rotated independently. The Harvesting Tool has two curved Jaws. One Jaw contains the heating elements for branch cutting and sealing; the second Jaw is longer and has a serrated inner edge. Cutting and sealing of vessel branches is achieved in two steps: (1) capture of the branch between the Jaws of the Harvesting Tool and then (2) simultaneous coagulation and ligation of the branch with the Jaws using direct current. Both steps are achieved by mechanical application of the Activation Toggle. Positioning of the device, cutting, and sealing are performed under endoscopic visualization. This device is intended for specific use with the VasoView® HemoPro™ Power Supply. |

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| **Indications for Use** | The VasoView® HemoPro™ System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall. |
| **Technological characteristics** | The Guidant VasoView® HemoPro™ Endoscopic Vessel Harvesting System incorporates the same fundamental scientific technology as the predicate devices. |
| **Performance data** | The results of the verification testing demonstrate that the Guidant VasoView® HemoPro™ Endoscopic Vessel Harvesting System meet the established acceptance criteria and performs in a manner equivalent to the predicate devices. No new safety or effectiveness issues were raised during the testing program. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Ms. M. Laurie Wong
Principal Regulatory Affairs Associate
Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, California 95054

Re: K052274
Trade/Device Name: Guidant Vaso View® HemoPro™ Endoscopic Vessel Harvesting System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 19, 2005
Received: August 22, 2005

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucheit for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):__K052274

Device Name:_VasoView® HemoPro™ Endoscopic Vessel Harvesting System

Indications For Use:
The VasoView® HemoPro™ System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD for MKM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K052274